ATTACHMENT 9

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Lead Case No. 3:21-cv-03825-VC

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IN RE: Da Vinci SURGICAL ROBOT ANTITRUST LITIGATION

----------x

AND RELATED CASE.

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March 15, 2023
9:07 a.m.

Remote Virtual Zoom Deposition of KIMBERLY A. TRAUTMAN take Plaintiff, pursuant to Notice, with the Witness located at the offices of Covington & Burling 850 Tenth Street NW, Washington, D.C., before William Visconti, a Shorthand Reporter and Notary Public within and for the State of New York.

discussions, I'm sure there were. Whether that specific question was asked outright, I don't remember.

Q. Do you remember whether when you were doing your work for Trautman International Services on the general consulting side, whether any clients came to you and said, we are trying to figure out whether we qualify as a re-manufacturer under the Quality System Regulation?

A. I do not remember any remanufacturing discussions per se under those couple of months under Trautman International Services, no.

Q. What do you mean by per se?

A. I'm sorry, I have to ask the court reporter to read it back please.

Q. That's okay, I won't make you stop what you're doing.

You said you do not remember any remanufacturing discussion per se under those couple of months. That is what you just said. And I was trying to understand what you meant when you said per se in that answer?

A. It was really just I'm trying to think of some of the clients that I had discussions of servicing and whether the topic of remanufacturing came up particularly. I don't think so, but I don't remember.

Q. So did you have clients who you characterized an engaged in servicing?

A. I had clients that had servicing as part of their quality management system, yes, sir.

Q. What is your definition of servicing in this context?

A. Servicing is capital equipment that has either preventive maintenance or other mechanisms by which the device comes back to a particular center, whether that be the client's or a subcontracted arranged service center. And typically there is checklist of looking at what the device is as it arrived into the service center. There is procedures and protocols as far as cleanliness and so forth both for the safety of the workers as well as further progressing into ensuring that there is appropriate cleaning and cleaning disinfection.

Sometimes there is wear out failures, other types of component replacements and like I said, that is typically done according to set procedures and that's the type of servicing that I would be referring to.

Q. In your general consulting work for Trautman International Services, did you have any clients who came to you and said they were contemplating modifying a finished device in commercial distribution and asked you whether the modifications they had would significantly change the performance or safety specifications or intended use?

A. Yes, sir, there were those general discussion, yes, sir.

Q. What do you recall about those discussions? Do you recall any specific type of devices that you were asked to consult on on that topic?

A. I do. They had to do with different types of reusable scopes.

Q. When say reusable scopes, are you talking about scopes for colonoscopies, endoscopies?

A. The line of products was quite diverse, so they had everything from to endotoscopes to bronchoscopes, to a whole line of different reusable scopes for different purposes.

Q. Was the client that you're thinking of in that situation the original manufacturer of those scopes?

A. Yes, sir.

Q. When was that engagement?

A. Shortly after I had the LLC.

Q. How long did that last?

A. It was actually a continuation of some work from my previous employer who the client wanted specifically to continue my engagement and it was agreed upon, so that was a continuation. So, again, almost immediately since they were a current client.

Q. The company that you were talking about before, is that NSF International?

A. Yes.

Q. You were with NSF International for a little over five years from 2016 to 2021?

A. Correct.

more officially 2012 to 2015, '16 that program was formulated, signed off by the heads of agencies and really took off and it is now an official program for the different governments.

Q. Going back to NSF for a moment. You said one of the things that you did was you had consulting activities at NSF; is that right?

A. Yes, sir.

Q. And you said at some point while at NSF you started working with an OEM that had reusable scopes; is that right?

A. I did and it was more than one, but yes, there was one client that followed me per their request when I left, yes.

Q. You had other manufactures of reusable scopes besides the one that followed you to your LLC?

A. Yes.

Q. How many did you have?

A. Specifically for -- at least two and some of the companies had some scopes in their portfolio. It may not have been my major focus, but I would say there was probably at least between 2 to 4 or 2 to 5.

A. Regulatory and quality issues, yes.

Q. When you say quality issues, what are you thing of?

A. For me like you said they are very intertwined. In the biggest sense regulatory can cover everything. But also some people differentiate the quality management system and quality management system audit out separately from an application type of scope or deliverable.

Q. So focusing on your consulting work since you left FDA to the present, have you ever had any engagement with independent servicing organizations?

A. Not since I left FDA prior to this case.

Q. Have you had any -- since you began your consulting in January of 2016 to the present, have you had any engagements that had any involvement with the da Vinci Surgical System?

A. No, sir.

Q. Have you had any engagements since January, 2016 that relate -- that have anything

to do with EndoWrist?

A. No, sir.

MR. MC CUAIG: Objection, Andrew, are you talking about just consulting arrangements in all of these questions?

MR. LAZEROW: Yes.

A. So not counting the case that we are talking about?

Q. Right.

A. Correct.

Q. Let's me ask it the other way.

MR. LAZEROW: Thank you, Dan, I appreciate the help there.

Q. Let me ask it this way. Is this case the only matter on which you provided any services that relates to the da Vinci Surgical System or EndoWrist?

A. Yes, I believe that is correct, right.

Q. You started at FDA in 1991?

A. Yes.

Q. Do I have it right, from 1991 until 1996 the focus of your efforts at FDA was the Quality System Regulation?

different commodities, not just medical devices.

And then when a different standards group opened up related to specific medical device standards, which is called Technical Committee, TC 210, I was involved with that and that was also around the 1994 timeframe. I was then given -- I was a branch chief in the Office of Compliance, I was a cardiovascular branch chief in the Office of Compliance in, gosh, maybe the '93, '94 timeframe. So I was also doing management of folks that were similar to some of the descriptions that I just gave you.

Then I was put on detail and led the effort to finalize the regulation to handle promulgation of the regulation, the preamble around, I think it was around the 1994 time.

Q. From 1991 until 1996 were you ever in the office of device evaluation?

A. No, sir.

Q. Have you ever been a lead reviewer on any 510(K) applications?

A. No, sir, not at all during my time

at FDA I was not lead reviewer in the Office of Device Evaluation.

Q. Were you a supervisor of any reviewers at your time at the FDA?

A. Was I -- yes, I just mentioned I was a supervisor in the Office of Compliance in the cardiovascular branch.

Q. When you were in that branch, did you have reviewers who reported up to you?

A. In the same reviewers as in a generic sense?

Q. No, reviewers of 510(K) applications.

A. Okay, I just wanted to make sure because there is a difference.

So I did not have 510(K) reviewers report up to me. We would issue consults to them. So I would be in charge of making sure that consults were sent to them and taking the outputs of those consults and furthering them into enforcement actions as appropriate.

Q. At the time that you were at FDA, am I right that the Office of Compliance and the Office of Device Evaluation were separate

offices within CDRH?

A. Yes, sir. Except for the -- in the in vitro diagnostic area, they were combined. But again, my position at that point was outside of that in vitro diagnostic life cycle division.

MR. LAZEROW: Let's make this a little easier on you. I'm going to mark tab 1 as Defendant's Exhibit 287. This is the expert report of Kimberly A. Trautman. You should have that in front of you and hopefully Dan has a copy also.

MR. MC CUAIG: I do.

MR. LAZEROW: We will mark that as DX 287.

(DX Exhibit 287 for identification, Expert report of Kimberly A. Trautman.)

Q. Do you have your report in front of you?

A. Yes.

Q. If you want to flip through it, is that a copy of report that you submitted in this matter on December 2nd, 2022?

A. Yes, sir, it looks like the report

all the way through even when I became the associate director for international, sometimes there I would be requested for consultations, but that would not have been my primary job. So roughly from '91 until that Novemberish, 2011 timeframe.

Q. Did you have a focus in any particular type of issues that the Office of Compliance was looking at with respect to potential enforcement actions?

A. No, sir, I would say that my experience ran the gamut.

Q. And so when you say ran the gamut, are you including your experience -- did you have experience in enforcement actions by the FDA vis-a-vis companies that did not have 510(K) clearance but the agency believed required it?

A. Yes, sir.

Q. Do you have any specific recollection of any particular types of devices where you had that kind of experience?

A. Oh my gosh. There has been to many enforcement -- so everything from

administrative actions -- so I will consider enforcement actions kind of run the gamut of administrative all the way through to judicial. So I was involved with many warning letters that had a variety of different allegations from lack of 510(K) to inadequate medical device reports, to lack of registration and listing to Quality System Regulations.

So administrative actions, civil money penalties. I worked on some of the agency's first 518 mandatory recall aspects. And I began several different aspects of a 518 A and E provisions. Worked on seizures, injunctions, criminal cases.

A lot of times those cases were not a single regulation violation. So often times there were multiple different regulations that were involved in those enforcement actions.

Q. Focusing on actions that involved an entity that did not have premarket clearance, but the agency believed it needed that clearance. Are you with me?

A. Yes, sir.

Q. Were you the person who determined whether the premarket clearance was required or not?

A. As explained earlier, I would have issued a consult out to the organization that specifically handled -- see there is particular divisions within even with the Office of Device Evaluation for 510(K) or in other regulations, for example the Office of Surveillance and Biometrics for medical device reports, we would issue, we being the Office of Compliance, would issue those consults out, pull it together, put the case together and then work with chief counsel on the totality of the case.

Q. Is the word consult a technical term of art in this context?

A. It's consultation. So it was a consultation process where there would be often times it would start off with some written, especially early on, a memo, in our days I'm sure it is more just an e-mail. But there would be a specific request to the other office as to this is the question, here is the evidence and here is what we would like you to

that I'm asking which is up until the point you get a consultation, a request for consultation, okay, and they say we want you to weigh in on whether this particular issue that I'm bringing to you requires premarket clearance. Okay. Are you with me?

A. So I'm with you, but in my experience the roles were more reversed. As we established, the majority of my earlier career was in the Office of Compliance and we would not always or it was not as common for us to get the consultation versus us to send out the consultation.

Q. What is the difference?

A. Well, the difference is in some of the roles that we just discussed as an international expert for quality systems, I may personally get a consultation request on a particular finding or piece of evidence or investigation and be asked to opine on whether this would constitute a nonconformance to this regulatory requirement related to the Quality System Regulation.

In the reverse, if someone in the

Office of Compliance had evidence that wanted to have -- the people that were directly responsible for a clearance or PMA approval, that consultation would go from the Office of Compliance to the Office of Device Evaluation and ask those questions and then be brought back to the Office of Compliance for case development.

Q. I'm focusing on the first part that you just talked about. The first situation where you get a consultation request on whether a particular finding or piece of evidence constitutes nonconformance with regulatory requirement. Okay. That's what I'm focusing on.

A. Okay.

Q. When you got that consultation, did you take any particular steps to satisfy yourself whether there was conformance or nonconformance with regulatory requirements?

A. Yes, I -- my responsibility would be to ensure that there was objective evidence and to make sure that objective evidence supported that quality system nonconformance. I was going to say and if I didn't find all the

were engaged in commercial activity?

A. I would have to ask you to define what you mean by commercial activity.

Q. What is your understanding of the phrase commercial activity?

A. I tried to give you that context by saying are they providing a service just like I provide a consulting service and charging for that service, yes.

Q. What is your understanding of whether Restore and Robotix were charging hospitals?

A. Were they charging hospitals, the evidence that I saw there was a charge for their activities, yes.

Q. So from your perspective they were providing a service to hospitals, right?

A. They were providing a service to the hospitals, yes, sir.

Q. So from your understanding of the phrase commercial activity, Restore and Robotix were engaged in commercial activity, right?

A. In the confines of the hypothetical that we discussed.

Q. Did you see anything that suggested they were a nonprofit?

A. I did not. You're talking about Robotix, no, I did not in any -- I had no indication. I just wanted to make sure we weren't talk about a nonprofit hospital.

Q. No, sorry. Apologies.

A. No, I didn't see any indication that those IRCs were nonprofit.

Q. The devices that they were servicing, the EndoWrists they were servicing, they were intended for use with patients; isn't that right?

A. I would assume so, yes.

Q. To your knowledge, do you know whether some of those devices that Restore or Robotix serviced were used with patients?

A. Again, I believe there is an assumption in the fact that there is evidence of their products going back to healthcare facilities. Was I able to or did I do any type of tracking to see that, no, that was not within the confines of the scope of my work in this case.

Q. Is it your understanding that these devices were not for the personal consumption of Restore and Robotix? Is that fair to say?

A. So Restore and Robotix were not going to perform surgery on themselves, that is correct.

Q. And the hospitals were, to your knowledge were using these devices to perform surgery on patients, right?

A. I would assume so, yes.

Q. You would also assume that these patients were paying the hospitals in some manner or form whether directly or through insurance for the surgery, would you agree with me on that?

A. Again, I would assume so, yes, sir.

Q. In preparation of your report that we are looking at which is marked as DX 287, what research, if any did you do into the meaning of the phrase held for sale or offered for sale?

A. I went back to the FDA website to

earlier in the day about how FDA officials have to do exploratory processes, how they need to investigate and that is what Mr. Lee was doing and he was exploring those and discussing how certain things might be remanufacturing and what he thought might be or what might not be later on, but ultimately when the discussions came to a collusion in July of 2022, there was no official determination that that activity was remanufacturing.

Q. At the time that you submitted your opening report in this matter, did you know there were other people at FDA who had told third-parties like Robotix and Restore that they considered their activities to be remanufacturing?

MR. MC CUAIG: Objection.

A. Again, I looked at several different documents, what I was focused on was what did FDA officials come out and did they give any official type of communication, was there any type of, it has come to our attention letter, was there any type of formal communication to an entity that said, according

to this provision of the law you're doing this and you should file a 510(K), letters that I have see many, many, many times throughout my career and I didn't see any of those in this case in the communications.

So informal communications that are happening between different officials throughout FDA, did I review them, were I aware of them, I cited some, others are in my reliance list, but again, I was focused for purposes of my review and report on what the agency came out as their official determination.

Q. What does it mean it has come to our attention letter?

A. So this is typically something when it was not through the inspection process that we had previously talked about this morning. During the inspection process an FDA investigator would have been able to collect different tangible objective evidence to lay out a scenario and if a 510(K) or other regulatory requirements were not being met, they could have gone to what is called a warning letter. But instead of going to a

warning letter or regulatory meeting administrative action, it's come to our attention letter was rather a step below that from administrative purpose. And that is where whether it be through promotional or advertising pieces of evidence, FDA may, again, just what it says, it may have come to their attention through different sources that this activity was ongoing and that that activity would require a particular compliance with a regulation or in this case a 510(K). And it would notify that recipient officially that this was the agency's thinking.

Q. Do you consider an it has come to our attention letter to be informal communication by FDA?

A. No, sir. They actually had -- it was titled -- it was an official correspondence. Now if might have been via e-mail, but on an FDA letterhead. It was not just discussions and e-mails going back and forth between individuals. And those letters -- it's come to out attention letters had different authorities as to who could signed those letters within the

agency.

Q. So from what you said, I take it it has not come to our attention that FDA sent an it has come to our attention letter to Robotix?

A. If one exists, I'd be happy to look into that further.

Q. Can you answer my question? It has not come to your attention as of today that the FDA sent an it has come to our attention letter to Robotix, correct?

A. Not that I remember off the top of my head.

Q. Looking back at paragraph 34 of your report. The Deutsche Bank report, you said you cited this in part because there were other folks who had come to the same view you had about whether that constituted remanufacturing or not, right?

A. As well as the question as to whether FDA was likely to take an enforcement action, both of those prongs were pertinent in that series with Deutsche Bank exhibits.

MR. MC CUAIG: Can we pause for a

second. I got text from Jeff Corrigan that he got bounced off the Zoom.

MR. LAZEROW: Let's go off the record.

THE VIDEOGRAPHER: The time is now 1:27 going off the video record.

(Recess taken.)

THE VIDEOGRAPHER: The time so now 1:29 back on the video record.

BY MR. LAZEROW:

Q. Who were the people who Deutsche Bank talked to for their report?

A. So my understanding was from the deposition of the gentleman who wrote the report was that he did not divulge the five experts that he had interviewed.

Q. So you don't know who those people actually are?

A. No, sir.

Q. Were you one of the people?

A. No, sir.

Q. Have you talked to anyone who told you they were one of the people?

A. No, sir.

Q. Did you do anything to investigate who those people were before you cited the Deutsche Bank report in your expert report?

A. Not outside of looking at the documents in the report and the deposition of the gentleman that wrote the report.

Q. Earlier you said that these were experts who were looking at the facts who agreed with you. Do you remember saying that?

A. Not exactly those words, but they were experts that were being asked to opine on whether the activities of third-parties doing the refurbishing functions that were described with da Vinci as to, A, whether a 510(K) was necessary and whether it was likely that FDA would have an enforcement action.

And again, one of the areas that I was focusing on in this report and the supplemental report was the whole concept that I was aware of in the discussions back from the '90s is whether the third-parties were actually providing a service to the hospitals and returning those devices to the hospitals or whether they were collecting and servicing and

putting them into commercial distribution via selling or reselling mechanisms.

Q. You do not know what information was available to the individuals that Deutsche Bank talked to at the time they talked with Deutsche Bank, right?

A. Not outside -- there was the report, there was graphs and PowerPoints and the deposition of the authors, the evidence that I had.

Q. The deposition of the author did not describe the information that was available to the people that he spoke to for that report, right?

A. Not exactly. If I remember correctly, he did go into some of the questions that he asked them, but I do remember the fact that he didn't remember or was unwilling, I honestly don't remember, but I have no knowledge of who the individuals that he consulted with, who they were.

Q. Does it matter to you who they were?

A. No. Again, I don't know what

qualifies as FDA experts. So my reliance on that was more on the fact that there were other people who in some way, shape or form had been qualified as expertise in that area and they were thinking and asking the same questions that I were and they came to a similar conclusion.

Q. Qualified by Deutsche Bank?

A. It could have been a consortium like GLG or Guidepoint or other folks. I know I have opined for investment companies on issues similar to this. Not anything to do with this particular issue. It could have been -- they could have been vetted through another consortium.

Q. Do you know what standard Deutsche Bank used to determine that these folks were FDA experts?

A. Not outside of the testimony from the author.

Q. Do you know what information they were given to review before they talked with Deutsche Bank?

A. Again, I know what he talked about

as far as the interviews. I don't know if he gave them or provided them any tangible websites or anything. I just know from his testimony that he had given scenarios and given information to them and on that information they provided an opinion.

Q. So the sum total of what you know about that report is the report itself and the deposition of the author, is that a fair statement and the exhibits used at the deposition, is that a fair statement?

A. Yes, sir. Again if the PowerPoints and some of the graphs and so forth are all considered up, I used the report in the bigger sense, because I remember there was a couple of different formats that that information was presented.

Q. Do you know if the people that Deutsche Bank spoke to spoke to the FDA before they gave their views to Deutsche Bank?

A. I do not know that one way or the other.

Q. Have you talked to anyone at FDA since you have been retained in this matter

previously marked.)

Q. Can you take out exhibit tab 35. Tab 35 has already been marked as Defendant's Exhibit 268.

A. Yes, sir.

Q. Do you have DX 268 before you?

A. I do, yes, sir.

Q. This is a letter from Mark Trumbore to Chris Gibson at Robotix dated November 16th, 2021, do you see that?

A. I do, yes, sir.

Q. You've never read this letter before today; correct?

A. It does not look familiar to me. So I would have to back and look at the list.

Q. You're welcome to do that. I will tell you it is not on either list attached to your report, right?

A. I will believe you because it doesn't -- sitting here right now it doesn't look familiar.

Q. I thought earlier you said you had not seen an it has come to out attention letter in that matter?

A. I mean, interesting that they did away with some of the formality, but the opening sentence does say it has come to our attention, yes, sir.

Q. This letter says, "it has come to our attention that you may be remanufacturing the da Vinci S EndoWrist Instruments which appear to meet the definition of a device as that term is defined in Section 201(h) of the Federal Food Drug and Cosmetic Act, (FD&C) in a manner that potentially violates the FD&C Act." Do you see that?

A. Yes.

Q. Do you know Mark Trumbore?

A. I know him not on a personal level, but I know that he is one of the supervisors.

Q. When you look at his signature, he appears to be the assistant director of the Division of General Surgery Devices; is that right?

A. That is correct, yes, sir.

Q. And in November of 2021 do you know who besides Mr. Trumbore would have to approve and sign off on an it has come to our

case, just in general. They said we are engaged in remanufacturing, we are going to submit a 510(K). So that's a -- they are taking this third-party, there is an original equipment manufacturer, has a 510(K) and they are taking a device that's already in commercial distribution, they are remanufacturing it and they are going to submit a 510(K).

You would not characterize that 510(K) by that third-party as a catchup 510(K)?

A. I would not.

Q. So a third-party servicer could not submit a 510(K)? Like if someone -- forget it, I got it.

At the time that you submitted your opening report in this matter, December 1st, 2022, were you aware that there was a product code for remanufactured EndoWrists?

A. I believe that product code came out after December 1st. So my answer is, I did not see the Iconocare 510(K) and I actually saw it first in trade press until after my first report.

Q. The Iconocare -- let's make sure we are on the same page. The Iconocare 510(K)

clearance came on September 30th, 2022 or end of September 2022. Is that consistent with your memory?

A. I honestly didn't remember the timeline, so then I was not aware of the Iconocare 510(K) until after I submitted the first report, I believe.

Q. You weren't aware of the product code?

A. Well the product code didn't exist until the Iconocare 510(K) came out.

Q. So at the time that you submitted your expert report in this matter you were not aware of the QSM product code?

A. I honestly don't remember from the past couple of -- the past two, three months between the two different reports when that came into play. I have to go back and look at the reliance list to see.

Q. Do you want to look at your reliance list on Exhibit 1?

A. I will be happy for you to tell me one way or the other.

Q. You cite to the Iconocare letter,

third-parties who were engaged in remanufacturing as that term is defined in the Quality System Regulation?

MR. MC CUAIG: Objection to the form.

A. Can you ask the question again, please?

Q. Do you agree that FDA continues to this day to enforce existing requirements to third-parties engaged in remanufacturing as that term is defined in the QS Regulation?

MR. MC CUAIG: Objection to the form.

A. I was say if the agency has determined a manufacturer to be a manufacturer or a re-manufacturer, then the applicable regulatory requirements are applied.

Q. You reference in your report the 510(K) regulation. Are you familiar with that?

A. 807 in general you mean, yes, sir.

Q. Were you involved in drafting that regulation?

A. No, sir.

Q. I can't remember back to this